EXHIBIT 5

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United States District Court,
N.D. Illinois, Eastern Division.

IN RE: ZIMMER NEXGEN KNEE IMPLANT PRODUCTS LIABILITY LITIGATION
Kathy L. Batty, Plaintiff,
v.
Zimmer, Inc., Zimmer Holdings, Inc., and Zimmer Orthopaedic Surgical Products, Inc., Defendants.

MDL No. 2272
|
Master Docket No. 11 C 5468
|
No. 12 C 6279
|
Signed August 25, 2015

MEMORANDUM OPINION AND ORDER

Rebecca R. Pallmeyer, United States District Judge

***1** Kathy Batty is one of hundreds of Plaintiffs to sue Defendants, Zimmer, Inc. and its affiliates (collectively, "Defendant" or "Zimmer"), manufacturers of the Zimmer NexGen Flex knee system. Plaintiffs, who have had the NexGen Flex system implanted, allege that the femoral and tibial components of the system are prone to premature aseptic loosening (that is, loosening which occurs in the absence of infection), resulting in pain and loss of movement. Ms. Batty's case has been chosen for a "bellwether" trial. Both parties have identified several expert witnesses. The court has already addressed challenges to a number of these experts in earlier rulings.[1] In this opinion, the court considers Plaintiff's objections to expert testimony from one of Zimmer's proposed experts, Dr. Michael G. Vitale [1337]. For the reasons set forth below, the court overrules Plaintiff's objections.

BACKGROUND

In April 2009, Plaintiff Kathy Batty's treating physician, Dr. Alan Klein, performed total knee replacements ("TKRs," also known as "total knee arthroplasties" or "TKAs") on both of Ms. Batty's knees. He implanted a NexGen LPS–Flex Gender Solutions femoral component (the "NexGen Flex") and a NexGen Stemmed Tibial Component Option in each of her knees. These components are among the Zimmer "high-flex" components at issue in these lawsuits and are designed to enhance a patient's knee flexion capacity to as much as 155 degrees, significantly more than the flexion afforded by earlier implants, including Zimmer's own original knee implant model (the "NexGen Standard"). Just over a year after her surgeries, in July 2010, Ms. Batty began to experience pain in both knees. Another orthopedic surgeon, Dr. Lawrence Crossett, performed revision surgeries to replace the Zimmer implants in April and May of 2011. Ms. Batty alleges in this litigation that the Zimmer high-flex design caused the premature loosening in her knees that required revision surgeries.

According to Plaintiff, a number of clinical research studies support the theory that Zimmer high-flex implants fail at an "artificially high rate when compared to their non-flex equivalents." (Pls.' Master Long Form Complaint [211] ¶ 125.) Zimmer's proposed expert, Dr. Michael G. Vitale, concedes that some peer-reviewed studies suggest that Zimmer NexGen Flex knee systems are associated with higher rates of revision. (Expert Report of Dr. Michael G. Vitale, Ex. A to Mem. in Supp. of Pls.' Steering Committee's Mot. to Excl. Test. of Michael Vitale [1339–1], hereinafter "Vitale Rep.," 8); *see* H.S Han et al., *High Incidence of Loosening of the Femoral Component in Legacy Posterior Stabilized–Flex Total Knee Replacement,* 89–B J. BONE JOINT SURG. 1457, 1461 (2007) (hereinafter "*Han–1* "); H.S. Han et al., *Brief Follow-up Report: Does High–Flexion Total Knee Arthroplasty Allow Deep Flexion Safely in Asian Patients*? 471 CLIN. ORTHOP. & REL. RES. 1492, 1497 (2013) (hereinafter "*Han–2* "); and S.–D. Cho et al., *Three- to Six–Year Follow-up Results After High–Flexion Total Knee Arthroplasty: Can We Allow Passive Deep Knee Bending?* 19 KNEE SURG. SPORTS TRAMATOL. ARTHROSC. 899, 903 (2011) (hereinafter "*Cho* "). Dr. Vitale responds to those studies with a review of data from an Australian joint replacement data registry and a literature review that he believes demonstrates that the unfavorable findings are outliers. Dr. Vitale asserts that most clinical studies report high success rates for Zimmer high flex devices. Plaintiff objects to Dr. Vitale's testimony on the grounds that, as a pediatric spine surgeon, he lacks the necessary qualifications to offer an opinion in this case and that the methodology of his literature review is biased and unreliable. In advance of bellwether trials, Plaintiff urges the court to exercise its

"gatekeeper function" and exclude the testimony of Dr. Vitale from Plaintiff's trial on the basis that it fails to meet *Daubert*'s strictures. (Mem. in Supp. of Pls.' Steering Committee's Mot. to Excl. Test. of Michael Vitale [1338], hereinafter "Pl.'s Mem.," 1.) Though the court shares some of Plaintiff's concerns, it ultimately concludes that Dr. Vitale's testimony would assist the jury and will be sufficiently reliable. The motion to bar his testimony will be denied.

DISCUSSION

I. *Daubert* Standards

***2** Rule 702 of the Federal Rules of Evidence, which governs the admissibility of expert testimony, states:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

In *Daubert v. Merrell Dow Pharm., Inc.,* 509 U.S. 579 (1993), the Supreme Court held that the Federal Rules of Evidence "assign to the trial judge the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Id.* at 597. This inquiry involves a "three-step analysis," which asks "whether the witness is qualified; whether the expert's methodology is scientifically reliable; and whether the testimony will 'assist the trier of fact to understand the evidence or to determine a fact in issue.' " *Myers v. Illinois Central R. Co.,* 629 F.3d 639, 644 (7th Cir.2010) (quoting *Ervin v. Johnson & Johnson,* 492 F.3d 901, 904 (7th Cir.2007)); *see also Lapsley v. Xtek, Inc.,* 689 F.3d 802, 809 (7th Cir.2012) ("Rule 702 requires that expert testimony be relevant, reliable, and have a factual basis—equirements that must be met before the jury is allowed to hear and perhaps be persuaded by the expert testimony.").

Daubert teaches that the reliability of an expert's methodology may be assessed by considering factors such as "(1) whether the scientific theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether a particular technique has a known potential rate of error; and (4) whether the theory or technique is generally accepted in the relevant scientific community." *Schultz v. Akzo Nobel Paints, LLC,* 721 F.3d 426, 431 (7th Cir.2013) (citing *Daubert,* 509 U.S. at 593–94). *Cf. Stollings v. Ryobi Technologies, Inc.,* 725 F.3d 753, 766 (7th Cir.2013) ("Rule 702's reliability elements require the district judge to determine only that the expert is providing testimony that is based on a correct application of a reliable methodology and that the expert considered sufficient data to employ the methodology."). Once an expert has identified a reliable methodology, the expert still must "faithfully apply the method to the facts at hand," and "rely on 'facts or data,' as opposed to subjective impressions." *Brown v. Burlington N. Santa Fe Ry. Co.,* 765 F.3d 765, 772 (7th Cir.2014). The test for reliability is a flexible one, however, *Lapsley,* 689 F.3d at 810, and the trial judge may, but need not, consider the specific factors identified in *Daubert.* The *Daubert* factors are important "where they are reasonable measures of the reliability of expert testimony," *Kumho Tire Co. v. Carmichael,* 526 U.S. 137, 152 (1999), but those factors do not apply "to all experts or in every case." *Id.* at 141. Further, in fulfilling its "gatekeeping" role, the trial court retains discretion in choosing *how* to assess the reliability of the testimony. *Id.* at 152.

***3** An expert's testimony is relevant under Rule 702 if "it assists the jury in determining any fact at issue in the case." *Stuhlmacher v. Home Depot U.S.A., Inc.,* 774 F.3d 405, 409 (7th Cir.2014). "Whether an issue is relevant in a case is a question of substantive state law; whether the specific evidence offered is relevant to resolving the issue is a procedural question governed by the Federal Rules of Evidence." *Stollings,* 725 F.3d at 767. Testimony may be relevant even where it involves "hypothetical explanation[s] of the possible or probable causes of an event." *Id.* (quoting *Smith v. Ford Motor Co.,* 215 F.3d 713, 718–19 (7th Cir.2000)). Ultimately, whether an explanation is credible in

light of the facts of the case is left to the trier of fact. *Id.* at 719.

Finally, "Rule 702's requirement that the district judge determine that the expert used reliable methods does not ordinarily extend to the reliability of the conclusions those methods produce—that is, whether the conclusions are unimpeachable." *Stollings,* 725 F.3d at 765–66 (citing *Daubert,* 509 U.S. at 595). An expert may provide expert testimony based on valid and properly applied methodologies and still present a "conclusion that is subject to doubt. It is the role of the jury to weigh these sources of doubt." *Id.* "[T]he accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.' " *Lapsley,* 689 F.3d at 805 (quoting *Daubert,* 509 U.S. at 596).

II. Report of Dr. Vitale

In his expert report, Dr. Vitale reviews data from two separate "references" to determine "whether there is some defect in the design of the [Zimmer high-flex] device[s] leading to consistent and replicable failure leading to higher rates of revision." (Vitale Rep. at 6.) Based on his "integrated review" of the two references—(1) data from the Australian Orthopaedic Association National Joint Replacement Registry and (2) his own "formal systematic review of the literature"—Dr. Vitale concludes that "there is no evidence that [the Zimmer] design is associated with higher rates of revision." (*Id.*) The Australian Joint Replacement Registry, Dr. Vitale explains, is a patient registry, or an "organized system" that collects uniform data to evaluate specified outcomes for a particular patient population. (*Id.* at 3.) Because of the size, representativeness, and heterogeneity of the data collected in a patient registry, clinical research on that data enables researchers to detect rare adverse events. (*Id.*) In Australia, all hospitals undertaking joint replacement procedures submit data to the Australian Registry, an entity established by the Australian Orthopaedic Association and funded by the Australian government. Australian Orthopaedic Assoc. Nat'l Joint Replacement Registry, *Annual Report* 3 (2013), *available at* https://aoanjrr.dmac.adelaide.edu.au/documents/10180/127202/Annual%B1Report%B12013?version=1.2&t=1385685288617 (last visited Aug. 24, 2015). As of 2013, 304 Australian hospitals were participating in the Registry, and the Registry reported on 351,875 primary total knee procedures. *Id.* at 3, 122. The Registry's principal outcome measure for all joint replacements is "time to first revision surgery." *Id.* at 4. The 2013 Australian Registry Annual Report, upon which Dr. Vitale relies, provides records of cumulative revision rates following total knee replacements for many knee devices, including Zimmer NexGen Flex devices. (Vitale Rep. at 5.)

Dr. Vitale's other "reference" is his systematic literature review. Such a review is not limited to any particular data registry and is, instead, an attempt to "synthesize and integrate the available relevant literature within a field" to answer some clinical question posed at the outset. (*Id.* at 4.) The review begins with a "formal, transparent, and reproducible" search for studies that address a proposed research question. (*Id.*) Once a list of appropriate articles is selected, the articles are reviewed and scored based on their methodological and evidentiary quality, and the review often concludes with summary statistics and qualitative findings. (*Id.*) Essentially, a systematic literature review uses formal search methods to allow a researcher to obtain a neutral "snapshot" of the existing research on a particular question.

***4** Plaintiff's motion to exclude Dr. Vitale's testimony does not mention his review of the Australian Registry Data, focusing instead on Dr. Vitale's qualifications to offer an opinion in this case and on the reliability of his literature review and its subsequent update. Dr. Vitale intended his literature review to examine the "current understanding regarding reported revision rates for NexGen Flex knee implants" and began with a search of relevant medical databases using a set of search terms related to his research question (such as "knee," "flex," and "NexGen"). (*Id.* at 8–9.) Dr. Vitale's initial search retrieved 3,437 studies. (*Id.* at 9.) Duplicate studies and irrelevant studies—such as those related to "ligamentous surgeries," "revision surgical technique," or "infections"—were ultimately excluded, leaving only 100 relevant studies to be analyzed. (*Id.*) Dr. Vitale divided the 100 studies into three groups: Group 1 reported outcomes for NexGen Flex knees, Group 2A reported outcomes for NexGen Standard knees, and Group 2B reported outcomes for other brands' high-flex knee implants. (*Id.*) Dr. Vitale's report omitted the results of 21 studies (eight from Group 1, ten from Group 2A, three from Group 2B) from his quantitative analysis for various reasons (*id.* at 9–11), namely that they had "some methodological or statistical or other inconsistencies that deserve some pause." (Dep. of Michael Vitale, Ex. B to Pl.'s Mem. [1339–2], hereinafter "Vitale Dep.," 179:10–22.) But Dr. Vitale does discuss the

excluded studies in the report and testified that the omitted studies were still "very much considered" in his qualitative analysis. (*Id.* at 179:3–22.) After discussing the reasons for omitting the excluded articles in each group, Dr. Vitale's report categorizes the remaining studies by their evidence level[2] and lists the "survival rates" (i.e., the percentage of TKAs that did not require revision) and average postoperative follow-up period (i.e., the period between operation and most recent follow-up) of subjects from the various studies. (Vitale Rep. at 9–12.) Dr. Vitale's review showed that most of the studies in Group 1 reported high survival rates and that reported rates for patients in Group 1 were similar to those in Groups 2A and 2B. He concluded that certain Group 1 studies with higher revision rates should be considered "outliers." (*Id.* at 13–14.) He thus concludes in the systematic review section of his report that "[i]f anything, NexGen Flex products appear to be as safe if not safer than other products of similar design." (*Id.* at 14.)

In his rebuttal to Dr. Vitale's report, Plaintiff's expert, Dr. Mininder S. Kocher, argues that Dr. Vitale failed to offer any analysis of whether patients who actually achieved high flexion were more likely to have revisions than those who did not. (Rebuttal Letter of Dr. Mininder S. Kocher, Ex. D to Pl.'s Mem. [1339–4], hereinafter "Kocher Rebuttal Rep.," 5.) As Dr. Kocher explained, and as Plaintiff contends in this case, patients with high flexion implants who do not actually achieve higher flexion may be no more likely to suffer from aseptic loosening than patients who have standard implants; it may be that only those patients in Group 1 who actually achieved higher flexion are more likely to suffer from such loosening and ultimately require revision surgery. (*Id.*) In response to the criticism that his analysis did not consider this possibility, Dr. Vitale reexamined the Group 1 studies already included in his review and provided an update to his report, this time including information about the range of motion achieved by patients in the studies. (Ex. Q to Pl.'s Mem. [1339–17].)

Plaintiff is not satisfied by this additional analysis. She contends that Dr. Vitale's lack of experience and knowledge about knees and knee replacement surgery disqualifies him from offering an expert opinion in this case. She urges, further, that his failure to follow established guidelines or to otherwise use proper methods in conducting his systematic literature review renders unreliable any opinion based on that review or its later update. Plaintiff also seeks to exclude Dr. Vitale's subsequent "range of motion" analysis as unreliable. The court addresses these arguments in turn.

A. Qualifications

Dr. Vitale is an orthopedic surgeon who specializes in pediatric spine surgery at Morgan Stanley Children's Hospital of New York–Presbyterian / Columbia University Medical Center, where he has been an attending orthopedic surgeon since 2001. (Vitale Rep. at 1.) He received his medical degree from Columbia in 1995. (*Id.*) After medical school, he completed a residency in orthopedic surgery at Columbia / New York Presbyterian Hospital in 2000 and a fellowship in pediatric orthopedic surgery at Children's Hospital of Los Angeles in 2001. (*Id.*) In addition to his experience as an orthopedic surgeon, Dr. Vitale also has a "special interest and expertise in the area of clinical research." (*Id.*) He received a master's degree in public health, with an emphasis on clinical outcomes research, from Columbia University in 1995, and he is the author of many peer-reviewed articles that "utilize techniques in health services research including large database review and systematic review of [medical] literature...." (*Id.*) He has served on the Evidence–Based Medicine Committee of the American Academy of Orthopedic Surgeons (*id.*), and he estimates that he devotes 20 to 25% of his workweek on clinical research. (Vitale Dep. at 10:23–11:2.)

***5** Plaintiff emphasizes that Dr. Vitale is a pediatric spine surgeon. As she sees things, his lack of experience with, prior knowledge of, and prior interest in knees and knee replacement surgery renders him unqualified to offer his opinion in this case. (Mem. by Pls.' Steering Committee in Supp. of Mot. for Misc. Relief [1338], hereinafter "Pl.'s Mem.," 4–7.) Dr. Vitale admits that he has never published a clinical research study on adult knees or on TKAs, and that he has not conducted a TKA himself since he was a medical resident in 2001. (Vitale Dep. at 20:12–18; 36:7–10.) In addition to this purported general lack of experience and knowledge of knees and TKAs, Plaintiff notes Dr. Vitale's lack of familiarity with Zimmer's or its competitors' devices and argues that this, too, precludes his offering an opinion about the safety of Zimmer's high-flex devices relative to other products. (Pl.'s Mem. at 6.) For example, Plaintiff notes that Dr. Vitale could not say whether Zimmer's gender-specific device was available in cruciate-retaining ("CR") form or in legacy knee posterior stabilized ("LPS") form; he did not know how long the LPS–Flex and CR–Flex devices have been on the market; he explicitly admitted that he "would not hold [himself] out as an expert" on the knee designs of Zimmer's competitors; and he confused the anterior and the

posterior cruciate ligaments during his deposition. (*Id.* at 6–7.)

Despite these shortcomings, the court is satisfied that Dr. Vitale possesses "scientific or specialized knowledge that will assist the trier of fact" in this case. FED. R. EVID. 702. As Plaintiff's own expert conceded, Dr. Vitale is "qualified as an epidemiologist." (Dep. of Mininder Kocher, Ex. C to Zimmer's Resp. to Pls.' Steering Committee's Mot. to Excl. Test. of Michael Vitale [1444–3], hereinafter "Kocher Dep.," 298:18–23.) In determining whether his testimony is admissible, the court compares "the area in which [he] has superior knowledge, skill, experience, or education with the subject matter of [his] testimony." *Carroll v. Otis Elevator Co.,* 896 F.2d 210, 212 (7th Cir.1990). The testimony Dr. Vitale intends to offer is not based on specialized knowledge of knee mechanics, surgical procedures, or the engineering design of Zimmer's products and those of its competitors. His testimony instead focuses on his review of clinical research—a discipline in which he has significant interest, knowledge, and expertise. The examples of Dr. Vitale's ignorance or misstatements cited by Plaintiff are not relevant to the clinical research reviews he conducted in this case. His conclusions are based on his epidemiological and general clinical research expertise, and the fact that his past clinical research did not specialize in the subjects of knees or TKAs does not disqualify him from offering his conclusions. *Cf.* *Gayton v. McCoy,* 593 F.3d 610, 617 (7th Cir.2010) (holding doctor did not need specific cardiac training to testify as expert in case involving heart-related death). [3]

B. Reliability of Dr. Vitale's Opinion

In addition to challenging Dr. Vitale's qualifications, Plaintiff argues that Dr. Vitale employed unreliable methods to reach his conclusions. Though she does not question his analysis of the Australian Registry data, Plaintiff asserts that Dr. Vitale's self-described "formal systematic literature review" did not adhere to widely accepted guidelines for such reviews and was conducted in a biased and unreliable way. (Pl.'s Mem. at 7–20.)

***6** The court ultimately agrees with Zimmer that the issues Plaintiff raises miss the big picture. (Zimmer's Resp. to Pls.' Steering Committee's Mot. to Excl. Test. of Michael Vitale [1444], hereinafter "Def.'s Resp.," 13.) Even cumulatively, though the issues Plaintiff raises may undermine Dr. Vitale's ultimate conclusions, they do not show that the methods he used were so unreliable that his testimony should be kept from the jury. On the contrary, as discussed below, the data Dr. Vitale collected will provide important context for the jury in deciding key issues in the case, and Plaintiff will have the opportunity through cross-examination and the production of contrary evidence to challenge his opinions.

In determining whether Dr. Vitale's testimony is sufficiently reliable, the court focuses on the "validity of the methodology employed ... not the quality of the data used in applying the methodology or the conclusions produced." *Manpower, Inc. v. Ins. Co. of Pennsylvania,* 732 F.3d 796, 806 (7th Cir.2013). Notably, Plaintiff does not contend that a formal systematic literature review is itself an unreliable or invalid methodology. Rather, she argues primarily that the literature review Dr. Vitale conducted for purposes of this litigation did not comply with internationally recognized guidelines outlined in Alesandro Liberati et al., *The PRISMA Statement for Reporting Systematic Reviews and Meta–Analysis of Studies That Evaluate Health Care Interventions: Explanation and Elaboration,* PLOS MED. 1 (July 2009) (hereinafter "PRISMA" or "PRISMA guidelines"). In addition to the PRISMA-specific defects Plaintiff asserts, Plaintiff claims that Dr. Vitale's literature review impermissibly "commingled" heterogeneous studies, failed to established a fixed definition of a knee device's "survivability," and used inconsistent criteria in determining which studies to include in his review; each of these alleged flaws, according to Plaintiff, shows that Dr. Vitale's methods were unreliable. Finally, Plaintiff urges that Dr. Vitale's analysis of study patients' range of motion was unreliably "tacked on" to his initial systematic review, again without adhering to systematic review guidelines. The court first discusses Dr. Vitale's purported failure to abide by the PRISMA guidelines before turning to the other methodological defects Plaintiff identifies.

1. Guidelines for Systematic Literature Reviews

Plaintiff and Zimmer disagree about the significance of the PRISMA guidelines. According to Plaintiff, PRISMA is the "international recognized guideline for systematic reviews" (Pl.'s Mem. at 8), and Dr. Vitale's deviation from PRISMA's 27–item checklist—by, for example, failing to explicitly state his study question, failing to acknowledge the limitations of his review, failing to present his findings graphically, and failing to reproduce his search results—demonstrates that he has not applied the "same level of intellectual rigor" as would someone in his field, making his

review unreliable. (*Id.* at 9 (citing *Lapsley,* 689 F.3d at 805).) Zimmer and Dr. Vitale respond that the PRISMA guidelines on which Plaintiff relies relate primarily to the *presentation* or *reporting* of systematic literature reviews, not to the process for conducting such a review. (Def.'s Resp. at 5; Vitale Dep. 238:23–240:7.) As Dr. Vitale was not disseminating his findings to a wider audience, but was merely conducting his review as part of an integrated report for this litigation, Zimmer argues, the PRISMA reporting guidelines have less applicability. (Def.'s Resp. at 5.) Furthermore, Zimmer disputes that Plaintiff has established that the PRISMA guidelines are as widely recognized as her attorneys claim. (*Id.* at 5–6.)

***7** The court sides with Zimmer on the issue of PRISMA's relevance to Dr. Vitale's review. In discussing the appropriate methodology for a systematic literature review, Plaintiff's own expert, Dr. Kocher, neglected to cite PRISMA, which casts some doubt on Plaintiff's claim of widespread acceptance. (*See generally* Kocher Rebuttal Rep.) In addition, the authors of the PRISMA Statement themselves caution that "PRISMA is not intended to be a quality assessment tool and it should not be used as such." PRISMA at 22. They also state quite explicitly that, as Dr. Vitale observed, PRISMA is intended to guide the *reporting* of systematic reviews and "does not address directly or in a detailed manner the *conduct* of systematic reviews." *Id.* at 4 (emphasis added).

The court's concern in this case is whether Dr. Vitale used reliable methods in conducting his review. Guidelines for *reporting* on such a review in a published academic journal may be of less concern in this context. PRISMA's requirement, for example, to include an abstract that will help readers to decide "whether to read the full report" is obviously not relevant here. More importantly, as discussed below, many of Dr. Vitale's alleged deviations from PRISMA relate to his reporting, rather than the conduct, of his literature review. The purpose for certain of the PRISMA checklist items is to reduce the potential for bias. *See, e.g.,* PRISMA at 7 (discussing how selection of review question might facilitate detection of bias). Reliability analysis under *Daubert* calls for the court to determine whether the expert's testimony is based on reliable methods rather than "his own subjective experience or bias," *Brown,* 765 F.3d at 775, so the court will consider whether Dr. Vitale's alleged deviations from the PRISMA guidelines did indeed introduce an impermissible element of bias or otherwise undermine his reliability. But Dr. Vitale's failure to abide by a particular checklist item suggested by PRISMA will not, by itself, render his literature method unreliable.

Plaintiff asserts that one of the most problematic deviations from the PRISMA guidelines in Dr. Vitale's report was his failure to include an explicit statement of the research question his review intended to answer. (Pl.'s Mem. at 9–11.) PRISMA guidelines explain that "precisely stated review objectives are critical as they help define other components of the review process" such as the study eligibility criteria and the search for relevant literature. PRISMA at 7. Dr. Vitale himself states that a systematic review's formal search strategy is "based on the research question." (Vitale Rep. at 4.) A primary reason for an explicit statement of the research question is that it enables subsequent researchers to determine whether the review is applicable to their interests. PRISMA at 7. That is not a concern for this litigation. One could imagine that the failure to state the research question driving a literature review might make it difficult for an observer to assess whether the proper studies were included or excluded. Here, however, though Dr. Vitale's report lacks a single, succinct statement of his research question, that question is readily discernible, and an external observer would be able to assess whether his review was properly tailored to answering that question. As Dr. Vitale stated in his deposition, his review sought to answer whether patients whose knees are replaced by Zimmer high-flex devices have higher rates of revision caused by aseptic loosening than do patients whose knees are replaced by other devices. (Vitale Dep. at 144:5–10.) Though this precise question is not clearly stated in his report, it is clear from the studies he includes and excludes and from his analysis of those studies that this is the question Dr. Vitale investigated. For example, Dr. Vitale omits from his quantitative analysis studies that excluded revised patients from their population or that included patients who needed revision but for whom the cause of that revision was unclear. (Vitale Rep. at 9–12.) And Dr. Vitale's analysis of the studies he deems relevant address the rate of revisions, attributable to aseptic loosening, for Zimmer high-flex devices and others. (*Id.* at 9–14.) Because the question that drove his review is easily identifiable, the court is comfortable concluding that Dr. Vitale's failure to include an explicit and succinct statement of that question in his report does not render his entire method unreliable.

***8** Plaintiff also faults Dr. Vitale for neglecting to acknowledge the limitations of his review. PRISMA guidelines provide that systematic reviews should discuss "limitations at study and outcome level (e.g., risk of

bias), and at review level (e.g., incomplete retrieval of identified research, reporting bias).” PRISMA at 21. According to PRISMA, “[r]eaders may find [such a discussion] helpful....” (*Id.*) In his deposition, Dr. Vitale noted that “systematic literature reviews, by design, have some limitations as [do] all research methodologies” (Vitale Dep. at 199:10–17), but he did not explicitly acknowledge any such limitations in his expert report. Plaintiff will have ample opportunity to press Dr. Vitale on the limitations of his report during cross-examination, however. *Cf. Buie v. McAdory,* 341 F.3d 623, 625 (7th Cir.2003) (whether a given expert witness overstated her conclusion can be explored on cross-examination). Dr. Vitale is clearly aware that systematic literature reviews have limitations, as he stated in his deposition, and Plaintiff has provided no reason why the court should conclude that his failure to state this fact in his expert report, as well, has any impact on the reliability of his underlying methods.

In addition to Dr. Vitale's purported failure to report his research question and to acknowledge his review's limitations, Plaintiff cites two more allegedly problematic deviations from the PRISMA guidelines: (1) the report's lack of graphic data explaining Dr. Vitale's findings and (2) Dr. Vitale's failure to reproduce his search results. The court concludes that neither issue renders Dr. Vitale's underlying method unreliable. Dr. Vitale's failure to include graphic data—specifically, box plots, forest plots or funnel plots [4] –is, again, an issue of the presentation, rather than the conduct, of his review. Furthermore, Dr. Vitale had a reason to omit graphical presentation of the data—namely, his reluctance to present data graphically when there is heterogeneity or variability among the studies included in his review. [5] (Vitale Dep. at 312:7–18.) Plaintiff's own expert criticized Dr. Vitale's report on this basis, but admitted that the results of a systematic literature review could be analyzed or interpreted in both quantitative *and* qualitative ways. (Kocher Dep. at 92:5–12.) Dr. Vitale's choice to present his data in a qualitative, non-graphical form, therefore, does not undermine confidence in his methodology. [6] Nor is the court moved by the contention that Dr. Vitale's failure to reproduce his search results discredits his entire review. Plaintiff urges that ensuring that the results are “transparent and reproducible” is “[a]xiomatic to a reliable systematic literature review,” and that Dr. Vitale's failure to make a list of studies he retrieved originally deprives the court of the ability to determine that his search and study selection were unbiased. (Pl.'s Mem. at 14.) Dr. Vitale's report does, however, clearly explain his search method, identifies the number of studies he initially retrieved and the ones he excluded, and describes his process for excluding certain studies (albeit without explaining the reasons for excluding or including any individual study). (Vitale Rep. at 8–9.) In addition, Dr. Vitale did produce his work product and search strategy document, which identified the dates on which the searches were run, the lists of articles selected for export from the databases searched, and the selected group of 331 “potentially relevant studies.” (Def.'s Resp. at 11; Garcia Email, Ex. G. to Def.'s Resp. [1444–7].) As Zimmer points out, “If Plaintiffs wish to challenge the validity of the reported search results or the choices to eliminate articles,” they are free to repeat the searches on the databases Dr. Vitale used. (Def.'s Resp. at 11.) Notably, as discussed below, Plaintiff has not identified a single relevant study that Dr. Vitale completely omitted from his review. Given this fact and given Dr. Vitale's transparency about the way his search was conducted and the information about the search strategy provided to Plaintiff, the court is satisfied that Dr. Vitale's failure to produce his original search results should not discredit the entire review.

2. “Commingling” of Heterogeneous Studies

***9** According to Plaintiff, one of the “deepest flaws” in Dr. Vitale's methodology is his “commingling” of studies that are highly variable, or heterogeneous, in terms of their “study length, follow-up, size, design, power, outcome, range of motion, component type” and other features. (Pl.'s Mem. at 12.) Dr. Kocher similarly opines that there is “significant variability” in the studies Dr. Vitale included in his review. (Kocher Rebuttal Rep. at 4.) He notes, for example, that the time between TKA and follow-up ranged among study patients from one month to 139.2 months, and points out that studies with one month follow-up are not useful for assessing revision rates. (*Id.*) Dr. Vitale himself did not provide heterogeneity statistics for the studies he included in his review, and Dr. Kocher suspects there is “likely large heterogeneity in the studies.” (*Id.*). This is problematic, he continues, because “[h]igh levels of heterogeneity preclude combining study results and making conclusions based on combining studies.” (*Id.*) Zimmer is untroubled by the heterogeneity concern. The examples Plaintiff identifies of “broad brush conclusions” that Dr. Vitale has drawn from the “commingled” studies are actually mere descriptions of the studies' findings, Zimmer contends. Those conclusions, Zimmer contends, do not rest on any impermissible inferences from combined data: Dr. Vitale simply states that “xx number of studies with xx months of follow-up reported xx%

survival." (Def.'s Resp. at 13.) Dr. Vitale in fact acknowledges that "the variability among study cohorts precludes aggregate analysis...." (Vitale Rep. at 4.) Thus, rather than attempting such analysis, he offers an examination of "crude survival rates" to provide "an important snapshot of the performance of NexGen Flex Products." (*Id.*)

In light of Dr. Vitale's recognition of the heterogeneity in the studies, the court is not certain that, in grouping studies together and providing information about the number of studies within that group that reported a given survival rate, Dr. Vitale was drawing any impermissible conclusions. (*Cf.* Kocher Rebuttal Rep. at 4.) This is not to say, however, that the heterogeneity of the studies included in Dr. Vitale's review is unproblematic. Some of the studies included may, as Dr. Kocher suggests, have follow-up periods that are too short to draw conclusions about survival rates. And the studies may be too variable across a number of dimensions to support Dr. Vitale's ultimate conclusion—based on his literature review and the Australian registry data—that "there is no evidence that this design is associated with higher rates of revision." (Vitale Rep. at 6.) But it is not the court's role as gatekeeper to determine whether Dr. Vitale's ultimate conclusion is the right one: "the key to the gate is not the ultimate correctness of the expert's conclusions." *Schultz,* 721 F.3d at 431. As discussed below, Plaintiff has not shown that Dr. Vitale used an improper method to select the studies for his review. In challenging the conclusions he draws from those studies, Plaintiff cannot rely on the court's assessment of the truth of those conclusions but may rely instead on "[v]igorous cross-examination [and] presentation of contrary evidence...." *Daubert,* 509 U.S. at 596.

3. Definition of "survivability"

Plaintiff contends, next, that in his examination of "survival rates among high flex knees," Dr. Vitale never defined "survivability" and thus was able to change his definition of patient survival from study to study, each time categorizing the data in a way that would favor Zimmer. (Pl.'s Mem. at 20–23.) This methodology, Plaintiff argues, is obviously not reliable. (*Id.*) But the examples Plaintiff cites do not actually demonstrate that Dr. Vitale's criteria changed or that he was inconsistent. Plaintiff's examples may suggest that the conclusions Dr. Vitale draws from his "survival analysis" are shaky, but they do not render his underlying methods unreliable. The court's *Daubert* analysis must focus "solely on principles and methodology, not on the conclusions they generate." *Daubert,* 509 U.S. at 595.

Dr. Vitale's "survival" criteria are consistent throughout his report. For each study, Dr. Vitale sought to determine "crude survival rates"—that is, the percentage of patients, at the time of the study's follow-up, who required revision following TKAs because of aseptic loosening. (Vitale Rep. at 4.) If the study reported no revisions at the given time of follow-up, or no revisions attributable to aseptic loosening, the survival rate was reported as 100%. (*Id.* at 10–12.) If a study reported revisions attributable to aseptic loosening, Dr. Vitale discussed those studies separately from those reporting 100% survival, and then determined the survival rate by counting the number of patients within the study who required revision because of aseptic loosening at the time of follow-up. (*Id.*) If a study reported revisions, but did not identify the percentage of revisions attributable to aseptic loosening, Dr. Vitale did not include that study in his quantitative analysis. (*Id.*) This appears to the court to be a consistent application of Dr. Vitale's definition of "survival." Plaintiff contends that Dr. Vitale's survival criteria should have led him to report the *Radetzki* study as showing an 85% (17 out of 20) survival rate as opposed to his reported 90% (18 out of 20) survival rate. (Pl.'s Mem. at 21 (citing Florian Radetzki et al., *High Flex Total Knee Arthroplasty—A Prospective, Randomized Study with Results After 10 Years,* 79 ACTA ORTHOP. BELG. 536, 540 (2013)).) But Dr. Vitale explained at his deposition that while three of the 20 patients required revision, only two out of 20 patients were revised for "asymptomatic aseptic loosening," while one additional patient was revised for "painful mid-flexion instability." (Vitale Dep. at 301:5–11.) And as discussed above, Dr. Vitale's survival criteria required a showing that the patient underwent a revision for *aseptic loosening*.

***10** Plaintiff also questions Dr. Vitale's inclusion of the *Ahmed* and *Nutton* studies in his survival analysis. She notes that Dr. Vitale made an assumption that the implants of those studies' patients survived despite any explicit statement about survival or revision rates from the authors. (Pl.'s Mem. at 21–22 (citing R.W. Nutton et al., *A Prospective Randomised Double-Blind Study of Functional Outcome and Range of Flexion Following Total Knee Replacement with the NexGen Standard and High Flexion Components,* 90–B J. BONE JOINT SURG. (BR.) 37, 42 (2008) and Issaq Ahmed et al., *Range of Flexion After Primary TKA: The Effect of Soft Tissue Release and Implant Design,* 32 ORTHOPEDICS 811 (2009)).) Aseptic loosening, Plaintiff contends, was not a

"primary or secondary endpoint" for either study—that is, the authors were not studying aseptic loosening, and their studies, therefore, should not have been included in the survival analysis. (*Id.* at 22.) Dr. Vitale's assumption about survivability is not unreasonable, in the court's view. As he explained, the studies were considering patients' range of motion following TKAs. The studies' authors reported follow-up data on patients with knee devices and did not make any mention of revisions; it was therefore reasonable to conclude that there were no revisions at all, whether as a result of aseptic loosening or for any other reason. (Vitale Dep. at 278:17–280:17.) Dr. Kocher questioned the strength of the conclusions one might draw from a study that did not mention revisions, but he acknowledged it was "fair to report" that such a study reported no revisions. (Kocher Dep. at 300:5–15.) At trial, Plaintiff is free to argue that one should give little weight to studies that require assumptions of this kind when making ultimate conclusions about survival rates. But the assumption Dr. Vitale made in including the studies within his analysis was at least a "fair" or reasonable one that does not make his methodology unreliable.

Plaintiff also faults Dr. Vitale for including the *Endres and Wilke* study among those listed as having 100% survivorship because that study's authors explicitly cautioned against drawing survivorship conclusions from their short-follow-up study. (Pl's. Mem. at 23 (citing S. Endres & A. Wilke, *High Flexion Total Knee Arthroplasty—Mid–Term Follow Up of 5 Years,* 5 OPEN ORTHOPAEDICS J. 138, 142 (2011) (hereinafter *Endres and Wilke*).) Dr. Vitale, however, did not draw grand "survivorship conclusions" on the basis of the *Endres and Wilke* study but was merely reporting that study's "crude survival rate" as part of his larger review. As Dr. Vitale said when discussing the *Endres and Wilke,* he "agree[s] completely in context that you cannot draw conclusions from any single study." (Vitale Dep. at 292:18–20.) Plaintiff can, on cross examination, question the wisdom of drawing larger survivorship conclusions from a review that includes such a study or of drawing conclusions from reports of "crude survival rates" generally. That said, though Plaintiff may have reason to believe that the ultimate conclusions Dr. Vitale draws from his literature review are "shaky," Plaintiff has not shown that the "survival" definition Dr. Vitale deployed in the conduct of his review was itself overly biased or unreliably inconsistent.

4. Study Inclusion and Exclusion Criteria

Plaintiff next argues that Dr. Vitale's review is "fatally flawed" because he used inconsistent criteria to determine which studies should be included in his review and which should be excluded. (Pl.'s Mem. at 14.) This allowed Dr. Vitale to "cherry pick" studies to produce an artificially favorable snapshot of the literature for Zimmer. (*Id.* at 16–20.) The court agrees with Plaintiff that testimony based on Dr. Vitale's literature review would have to be excluded if Dr. Vitale used biased inclusion or exclusion criteria to provide an inaccurate snapshot of the literature. Such a review would be unreliable and would mislead the jury. *Cf. In Re Zoloft,* 26 F.Supp.3d 449, 460–61 (E.D.Pa.2014) (excluding epidemiologist's testimony where she selectively discussed studies most supportive of her conclusions and failed to account for contrary evidence, including her own published work). The court, however, does not believe that Dr. Vitale engaged in such biased "cherry picking" in conducting his review.

Plaintiff faults Dr. Vitale for dismissing four publications —*Han–1, Han–2, Cho,* and R.S. Namba et al., *Increased Risk for High Flexion Total Knee Replacement with Thicker Tibial Liners,* 96–B BONE JOINT J. 217, 223 (2014) (hereinafter "*Namba* ")—with "alarmingly high" revision rates from his analysis. (Pl.'s Mem. at 16.) But Dr. Vitale did not "dismiss" those publications in the sense of excluding them from his review or pretending they did not exist. On the contrary, all four are cited and discussed within his report. Dr. Vitale excluded *Han–1* from his quantitative analysis of Group 1 (concerning Zimmer high-flex devices) because *Han–1* and *Han–2* used the same patient cohort, and in such cases, Dr. Vitale included only the study with the longer follow-up. (Vitale Rep. at 10.) Dr. Vitale excluded two other studies from the Group 1 quantitative analysis for this same reason. (*Id.*) As for Cho, contrary to Plaintiff's claims, Dr. Vitale did include that study within the Group 1 analysis. (*Id.*) *Namba,* on the other hand, was excluded from Dr. Vitale's quantitative analysis of Group 1.(*Id.*) Dr. Vitale did not exclude *Namba* because the results were unfavorable, however; he excluded *Namba* because the study reported a survival rate only with respect to "aseptic revision." (*Id.*) That is, it was not clear from *Namba* how many of the revisions were attributable to aseptic *loosening,* and he therefore concluded the study's results could not reliably be included in the quantitative analysis. Other studies were similarly omitted from the quantitative analysis because they did not provide serviceable data for quantitative review. For example, one study reporting a 100% survival rate was excluded because it discussed the misnomer "NexGen 'Full Flex' knees" and thus could not be

accurately categorized. (*Id.*) In any event, though he omitted the *Namba* results from the quantitative analysis, Dr. Vitale still considered the study, and it contributed to his opinion in the case. (Vitale Dep. 207:8–208:5.)

***11** Dr. Vitale did label the three cohorts studied in the four publications at issue (one cohort for *Han–1* and *Han–2,* one cohort for *Cho,* and one cohort for *Namba*) as "outliers." (Vitale Rep. at 10.) But he discussed each study and explained why he thought it deserved that label. The results of *Han–1* and *Han–2* were simply too disparate from the results of other studies to be given much weight, especially for a single cohort whose devices were implanted by a single surgeon at a single institution. (*Id.* at 13.) Though *Cho* reported high rates of loosening, it also reported high *survival* rates at a 51–month follow-up. (*Id.*) And analysis of the *Namba* results is confounded by the fact that the highest revision rates were found among patients given thicker tibial polyethylene liners—liners commonly used for patients with "instability and/or significant" deformity, which could have contributed to the high revision rates. (*Id.* at 10, 13.) These three "outlier" cohorts, thus, were considered and not simply ignored or dismissed out of hand. Plaintiff is free to challenge Dr. Vitale's characterization of these studies as "outliers" during cross-examination, but his treatment of these studies does not appear to the court to reflect unacceptable "cherry picking."

Plaintiff does bring to the court's attention problematic aspects of certain studies that Dr. Vitale may have overlooked in his inclusion and exclusion process. These oversights, too, may provide additional material for cross-examination. For example, Dr. Vitale included two studies in his Group 1 quantitative analysis, stating that both reported 100% survival rates, despite the fact that both studies used the same cohort and that Dr. Vitale had excluded previous studies for studying a duplicate cohort. (Vitale Rep. at 10.) Dr. Vitale explained at his deposition, however, that the authors of each study reported different numbers for the cohort sizes at the beginning of the studies, and thus the use of the same cohort "got by the peer-review process and it got by my filter as well." (Vitale Dep. 284:3–12.) This appears to the court to be an inadvertent oversight, not an attempt to distort the data. It is also easily correctable by removing one of the studies from the Group 1 analysis so that instead of 28 out of 35 studies reporting 100% survival rates, only 27 out of 34 do so.

Plaintiff also points out that nine of the 42 studies included in Dr. Vitale's Group 1 quantitative analysis focus on NexGen Flex *mobile-bearing* knees, devices that are not at issue in this litigation, which deals with Flex fixed-bearing knees. (Pl.'s Mem. at 19.) It appears that when Dr. Vitale conducted his review, he was unaware whether the Plaintiffs were suing over both types of Flex knees and thus may have included unrelated and irrelevant studies in his review. (Vitale Dep. at 75:16–24.) In his deposition, Dr. Vitale admitted initially that the inclusion of these studies was a mistake; but he later corrected his testimony to say that many of the included mobile-bearing studies have "serviceable relevant data for fixed components." (Vitale Errata, Ex. I to Def.'s Resp. [1444–9].) Zimmer responds to Plaintiff's argument by noting that there are, in fact, cases in this litigation involving mobile-bearing knees and that the mobile-bearing knee's femoral component is identical to the femoral component of other Flex devices. (Tr. of Proceedings, *Daubert* Hearing, Apr. 20, 2015, at 217:14–24.) The court concludes that the inclusion of these nine studies in Dr. Vitale's review, some of which included fixed-bearing knee devices as well, does not render Dr. Vitale's entire testimony unreliable. Dr. Vitale's conclusions, after all, are based on his review of both the Australian Registry data and the 100 relevant studies included in his review (50 studies specific to the NexGen Flex), and the court is unwilling to jettison testimony based on that extensive review on the basis that a handful of studies may not have been properly included. As with the duplicate cohort oversight, if Plaintiff believes these studies were improperly included, Plaintiff can easily remove the studies and perform her own quantitative analysis of the resulting data. The best way, therefore, to determine how the inclusion of these studies affects the ultimate conclusion to draw from Dr. Vitale's data is for Plaintiff to cross-examine Dr. Vitale and present evidence of the studies' purported irrelevance and allow the jury to weigh the competing arguments and draw its own conclusion.

***12** Dr. Vitale excluded both favorable and non-favorable studies from his review, apparently for objective, scientific reasons. Significantly, Plaintiff has not identified any apparently relevant study that Dr. Vitale should have discussed but omitted completely. Dr. Vitale is not therefore, as Plaintiff contends, like the excluded epidemiologist in *Zoloft* who failed to account for or discuss contrary evidence in her expert report. 26 F.Supp.3d at 460–61. On the whole, Dr. Vitale appears to have used reliable methods in including and excluding studies, and Plaintiff will be free at trial to dispute the conclusions one ought to draw from the studies Dr. Vitale collected.

5. Dr. Vitale's Subsequent "Range of Motion" Analysis

As noted, after Dr. Kocher criticized Dr. Vitale's report for failing to consider the range of motion achieved by patients in the studies included in his review, Dr. Vitale prepared an additional analysis of patients' range of motion in the 50 studies chosen for Group 1 of his initial review. Plaintiff asks the court to exclude this analysis because it was performed post-hoc and did not follow "any methodology of a systematic review." (Pl.'s Mem. at 23.) As the court understands Plaintiff's position, she argues that Dr. Vitale conducted his initial review to answer a question (whether Zimmer's high-flex devices in general have higher rates of revision caused by aseptic loosening than other devices) that did not consider the degree of flexion (or "range of motion") actually achieved by study patients. Now that he is attempting to address that specific question (whether patients who achieve higher flexion have higher revision rates), she contends, he is required to conduct a completely new systematic review with a search driven by this new question. Zimmer responds by pointing out that Dr. Vitale's subsequent analysis was a response to Dr. Kocher's criticism of the initial review on this ground—that is, that it did not consider whether patients in the Group 1 studies actually achieved high flexion. (Def.'s Resp. at 12.) It is thus "only fair" that the court would allow Dr. Vitale to go back and review those Group 1 studies to address Dr. Kocher's criticism. (*Id.*)

The court agrees with Zimmer. Dr. Vitale's subsequent analysis was not aimed at providing a definitive answer to the question of whether patients who achieve higher flexion with the Zimmer high-flex devices have higher revision rates because of aseptic loosening. Rather, Dr. Kocher suggested that the high survival rates Dr. Vitale reported for studies of Zimmer high-flex devices must be discounted because his report did not analyze the flexion achieved by patients in those studies, and Dr. Vitale simply revisited those studies to determine whether Dr. Kocher's attack had merit and updated his data accordingly. The court does not agree with Plaintiff that this "subsequent analysis" was invalid or unreliable.

C. Relevance of Dr. Vitale's Opinion

The court also concludes that the testimony Dr. Vitale intends to offer is relevant under Rule 702 because it will "assist the [jury] with its analysis of ... issues involved in the case." *Smith,* 215 F.3d at 718. Namely, Dr. Vitale's testimony will provide the jury with an opportunity to gain a picture, or "snapshot," of the existing medical literature related to the question of whether Zimmer's high-flex knee devices are more or less likely to lead to revision caused by aseptic loosening. Even if this picture does not allow the jury to answer what Plaintiff characterizes as the key question in this litigation—whether failure rates of Zimmer's high-flex devices are higher in those patients who actually achieve high flexion—this picture might inform their conclusions about whether Zimmer's design was indeed defective or whether Zimmer's design was a likely cause of Plaintiff's injury.

***13** The picture of the literature that the jury develops may not be identical to the one Dr. Vitale seeks to paint. Dr. Vitale's version of that picture shows that a substantial majority of relevant studies found that Zimmer's high-flex devices do not lead to revisions caused by aseptic loosening. He concluded that the handful of studies suggesting the opposite can be dismissed as outliers. Following cross-examination, however, the jury may conclude that Dr. Vitale dismissed studies like *Han* too easily, that studies showing high survival rates for Zimmer's high-flex devices should be discounted because of short follow-up times or failure to consider patients' degree of achieved flexion, or that Dr. Vitale's conclusions do not follow from his data for some other reason. But the underlying data Dr. Vitale provides, and the debate about his conclusions that will inevitably occur at trial, will surely assist the jury in analyzing key issues in the case. Dr. Vitale's testimony is therefore relevant under Rule 702 and *Daubert*.

CONCLUSION

The court concludes that Dr. Vitale is qualified as an epidemiologist and clinical researcher to offer testimony in this case. The testimony he intends to offer is relevant, and the methods underlying that testimony appear to be sufficiently reliable. Plaintiff's motion to exclude his testimony [1337] is therefore denied.

All Citations

Not Reported in Fed. Supp., 2015 WL 5050214

Footnotes

1 For purposes of this opinion, the court assumes familiarity with its detailed description of the facts of this case in earlier opinions. *See* *In re Zimmer NexGen Knee Implant Products Liab. Litig.,* No. 11–CV–5468, 2015 WL 3669933 (N.D. Ill. June 12, 2015); *In re Zimmer NexGen Knee Implant Products Liab. Litig.,* No. 11–CV–5468, 2015 WL 3799534 (N.D. Ill. June 17, 2015).

2 Dr. Vitale's report includes a table from the "Journal of Bone and Joint Surgery Guidelines for Level of Evidence," which lists five levels of evidence (with Level I as the highest level and Level V as the lowest) and the categories of studies within different study types that warrant the label of a particular evidence level. (Vitale Rep. at 25.) For therapeutic studies that investigate the results of treatment, for example, studies categorized as randomized control trials would provide Level I evidence, while case-control studies would produce Level III evidence. (*Id.*)

3 Plaintiff criticizes Dr. Vitale's reliance on help from a research assistant, Columbia medical student Evan Trupia, in the conduct of his review. It is unclear whether Plaintiff is arguing that Dr. Vitale's use of a research assistant warrants exclusion of his testimony because it is based in part on the work and opinions of an unqualified expert or because it simply shows his method to be unreliable. Whatever Plaintiff's theory on this point, the court does not believe that Dr. Vitale's employment of Trupia in his review was improper. "An expert witness is permitted to use assistants in formulating his expert opinion." *Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.,* 285 F.3d 609, 612 (7th Cir.2002). Dr. Vitale "designed, supervised the performance of, and conducted" the project. (Vitale Rep. at 8.) He stated that use of a research assistant in this fashion is common and that he has sought such assistance for other systematic literature reviews that have been subsequently published. (Vitale Dep. 145:9–17, 147:12–14.) Dr. Vitale closely supervised Mr. Trupia. (*Id.* at 189:22–190:3.) The court concludes that Dr. Vitale, not Mr. Trupia, is the only expert whose qualifications it must assess here and that Mr. Trupia's assistance does not undermine the reliability of Dr. Vitale's testimony.

4 As Dr. Vitale explained, each of these plots is a way of "graphically representing data." A box plot "give[s] you an estimate of the effect size as well as the confidence intervals around those effect sizes." (Vitale Dep. at 248:6–10.) A forest plot depicts "the relationship between study size and effect size." (*Id.* at 248:11–16.) A funnel plot "speaks to issues related to effect size, confidence intervals around those and sample size.... " (*Id.* at 248:20–24.)

5 Dr. Vitale does not explain precisely why the heterogeneity of studies would affect the decision to present data graphically. He does state, though, that "the question of how much summary statistics, how much pooled analysis, how much aggregate data to present ... is one that should be driven by the heterogeneity of the study.... " (Vitale Dep. at 250:17–20.) Dr. Kocher agreed with the statement that "variability among the different patient groups makes a pooled analysis ... not appropriate from an epidemiologic perspective." (Kocher Dep. at 93:9–13.)

6 Though Dr. Vitale has himself published a paper that presented data in graphical form, he states that such presentation was not his own personal choice and that since the publication of that article, "there's been more of an emphasis on restricting aggregate data presentations, including things like forest plots to studies where there was more homogeneity." (Vitale Dep. at 250:6–251:1.)